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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,726	01/24/2002	Gary K. Owens	021258-000200US	2786

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

13

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,726

Applicant(s)

OWENS ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17 and 19, drawn to an isolated, synthetic or recombinant polynucleotide comprising an SM-MHC promoter/enhancer capable of conferring smooth muscle specific expression *in vivo*, classified in class 536, subclass 24.1.
- II. Claim 18, drawn to a transgenic non-human animal comprising the polynucleotide of Group I, classified in class 800, subclass 8.
- III. Claims 20-33, drawn to a method of expressing a polynucleotide in a smooth muscle cell *in vivo* comprising introducing said polynucleotide operably linked to an SM-MHC promoter/enhancer sequence, classified in class 514, subclass 44.
- IV. Claim 34, drawn to a method for screening a compound that modulates the activity of an SM-MHC promoter, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid of Invention I is related to the transgenic animal of Invention II in that the animal can be produced with, and comprises the nucleic acid of Invention I. The animal is distinct from the nucleic acid, however, because they are physically and functionally distinct and the nucleic acid can be used for processes other than production of the transgenic animal, such as in hybridization assays. Furthermore, patentability of the transgenic animal arises from the phenotypic characteristics of the animal; thus,

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patentability of the transgenic animal is not solely dependent upon the particulars of the nucleic acid or polypeptide comprised within the animal.

The methods of Inventions III and IV are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the Groups are directed to methods of obtaining distinct objectives (i.e., expression of a polynucleotide versus identification of a modulatory compound) and clearly have different modes of operation, function and effect which are dictated by the different desired objectives. Although the method of expressing a polynucleotide of Invention III could be used together with the method of screening a compound of Invention IV, the SM-MHC promoter/enhancer used in the method of Group III is limited to being capable of conferring smooth muscle cell specific expression *in vivo*, while the SM-MHC promoter/enhancer used in the method of Group IV is not so limited. As the products used in the method of Group IV are of broader scope than the products used in the method of Group III, Group IV encompasses methods that are not capable of use together with the method of Group III.

Invention I is related to the methods of Inventions III and IV are as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as in a hybridization assay or to screen a library. Furthermore, as described above, the method of invention IV is not

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limited to using an SM-MHC promoter/enhancer capable of conferring smooth muscle specific expression *in vivo* and thus could be practiced using a promoter/enhancer that is materially different from the SM-MHC promoter/enhancer of Group I, which is limited to being capable of conferring smooth muscle specific expression *in vivo*.

Inventions II and III are distinct because the transgenic animal could not be produced according to the method of group II, which is limited to introducing the polynucleotide into a smooth muscle cell.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method for screening a compound could be practiced with a materially different product such as a cell in culture.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

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July 23, 2003